



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Elizabeth W. Mata
Hamilton, Brook, Smith & Reynolds, P.C.
530 Virginia Road
P.O. Box 9133
Concord, MA 01742-9133

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,218,108

MAILED
JUN 3 2010
ACFEP-OPLA

Dear Ms. Mata:

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,218,108 for a period of one (1) year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at raul.tamayo@uspto.gov.

Mary C. Tim
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: VOLUVEN® (6%
hydroxyethyl starch 130/0.4 in 0.9%
sodium chloride injection)
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Fresenius Kabi Deutschland GmbH :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 5,218,108 : INTERIM EXTENSION

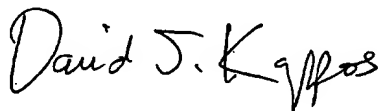
Fresenius Kabi Deutschland GmbH, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,218,108, filed an application for patent term extension under 35 U.S.C. § 156 on February 21, 2008. The original term of the patent is due to expire on June 8, 2010. The patent claims the active ingredient 6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection in the human drug product VOLUVEN® which was approved by the Food and Drug Administration for commercial marketing or use on December 27, 2007. An extension of 1,371 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,218,108 is granted for a period of one year from the original expiration date of the patent.

June 3, 2010

Date



David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office